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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,678	12/08/2003	Benjamin Oshlack	02755/0205241-US0	4265
7278	7590	07/09/2007		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER SILVERMAN, ERIC E	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 07/09/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/731,678

Applicant(s)

OSHLACK ET AL.

Examiner

Eric E. Silverman, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 80-106 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 80-106 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Response to Amendment***

Applicants' amendment after final rejection, filed 4/20/2007, has been received and is entered. Pursuant to amendment, claims 80 – 106 are pending. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

### ***Petition Under 37 CFR 1.48***

In view of the papers filed 4/20/2007, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(c). The inventorship of this application has been changed by addition of inventor Frank Pedi, Jr.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

### ***Response to Arguments***

Pursuant to the acceptance of the Petition under 37 CFR 1.48(c), the rejections discussed in the previous office action under 35 C.F.R. 103(a) are **withdrawn**, since the some of the art relied on for those rejections is no longer prior art as defined by the appropriate sections of 35 C.F.R. 102. The rejection for obviousness-type double patenting over US 5,965,161 is **withdrawn** in since an acceptable terminal disclaimer has been filed.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 80 – 84, 87 – 91, 93 – 100, and 102 – 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,126,684 to Robson et al., alone or as evidenced by US 3,758,680

Claim 80 requires a composition of matter including oxymorphone or a salt thereof, a hydrophilic polymer, a binder, and a diluent. Claim 81 requires that the dosage form contains granules having a diameter between 0.1 mm and 3 mm. Claims 82 – 83 require that an alkylcellulose, ultimately ethylcellulose, is present. Claim 84 requires a tablet, and claim 86 requires a matrix. Claims 87 – 88 require that the therapeutic effect be provided for about 12 hours or more and about 24 hours or more. This is *not* understood to mean that the drug must be released over this timeframe, only that some therapeutic effect be provided over this timeframe. Claims 89 – 91 and 93 – 95 are product by process claims which read on the products of claims 80 – 84. Claims 98 – 100 and 102 – 104 are methods of making the product by mixing the materials, granulating them, and incorporating the granules in a dosage form.

Robson teaches tablet dosage forms containing a PEG 6000 as a hydrophobic polymer, lactose as a diluent, and corn starch, talcum powder, and magnesium stearate as binders (Example 1). The powders are pressed through a screen with openings of 0.6 mm, thus there are granules present within the required range. The pressing through a screen reads on “subjecting to shear” in the method claims. In Example 2, the tablet is a matrix-tablet, containing an aqueous gelling matrix. Oxymorphone is

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specifically suggested as a drug for use in these dosage forms (claim 2). With regard to the timeframe of therapeutic effect, a composition having the same components is expected to have the same properties, since compositions and their properties are not separable.

Although it is not relied upon for the rejection US 3,758,680, which teaches that ethyl cellulose causes sustained release in pellets and granules when blended with active drugs (see example 5), is noted as evidence supporting the position that the compositions of Robson do indeed have the claimed properties.

Robson does not require the use of oxymorphone.

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use oxymorphone in Robson. The motivation comes from Robson, who claims an embodiment of the invention where oxymorphone is used. Since this is a claimed embodiment, the artisan would enjoy a reasonable expectation of success.

Claims 85, 92, 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robson et al, as applied to claims 80 – 84, 87 – 91, 93 – 100, and 102 –106, and in further view of US 4,524,060 to Mughal et al.

The teachings of Robson are discussed above.

What is lacking is a teaching of a capsule.

Mughal teaches sustained release compositions comprising ethyl cellulose, PEG (a hydrophilic polymer), talc (a diluent), and Kaolin Light BP (a binder). See Example 4. Mughal teaches that it is useful to provide such compositions as sustained release capsules for oral delivery (abstract).

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It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to provide the composition of Robson as a capsule. The motivation comes from Mughal, who recognizes the utility of capsules in providing similar drug formulations in the art. Since capsules are well-recognized in the art as an acceptable oral dosage form, the artisan would enjoy a reasonable expectation of success.

### ***Conclusion***


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric E. Silverman, PhD  
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SUPERVISORY PATENT EXAMINER  
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